



208 Burwash Avenue
Savoy, IL 61874

K131428
Page 1 of 3

JUL 16 2013

Section 5
510(k) Summary

- (1) **Date Summary Prepared:** 04/29/2013
Traditional 510(k) Submission
- (2) **Submitter:** Acoustic MedSystems, Inc. Tel: 217-239-0900
208 Burwash Avenue Fax: 217-239-0905
Savoy, IL 61874
- Establishment Registration No.: AMS will register following
FDA clearance
- Contact Person: Jennifer Williams
FDA Official Regulatory
Correspondent
e-mail: jwilliams@acousticmed.com
- (3) **Device Name:** RadVision
- Common Name:** Brachytherapy Dose Planning and Treatment System
- Classification Name:** 21CFR 892.5050 Medical charged particle radiation therapy
system, Class II.
- Product Code:** MUJ
- Proprietary Name:** RadVision
- (4) **Legally Marketed Predicate Devices:**
- Burdette Medical Systems, Inc. Interplant,
510(k) number K982696 dated 1 April 1999
- Varian Medical Systems BrachyVision 6.0,
510(k) number K992762 dated 03 March 2000
- Varian Medical Systems VariSeed 7.1,
510(k) number K030534 dated 21 May 2003

Telephone: 217-239-0900
Facsimile: 217-239-0905

(5) **Description of Acoustic MedSystems, Inc. RadVision Dose Planning and Treatment System:**

The RadVision system is a brachytherapy dose planning and treatment guidance system. The system consists of a computer, video capture device and software tools. The required software tools are installed in the computer. The system can be used for pre-treatment real-time dose planning in the Operating Room (OR), and for permanent seed implants performing post-implant seed localization assessment and post-implant dose distribution analysis.

(6) **Intended Use:**

The intended use of Acoustic MedSystems, Inc. RadVision Dose Planning and Treatment Systems is to provide patient-specific planning, imaging, and implants or applicator device alignment for treating cancer using radioactive seed implants or high dose radiation (HDR) afterloader devices. In addition to planning and treatment, RadVision allows volume and dose calculations, 2D and 3D anatomy and dose visualizations, as well as post treatment seed localization.

RadVision is a general purpose brachytherapy planning system used for prospective and confirmation dose calculations for patients undergoing a course of brachytherapy using either temporary or permanent implants of various radioisotopes.

(6) **Performance Testing:**

The computer systems that will be used to install RadVision for commercial distribution to customers are required to be tested and meet the following standards:

- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-3
- IEC 60601-1-4

Verification and Validation test procedures were prepared considering the technological characteristics of the predicate devices. Non-clinical testing of RadVision was conducted for the following characteristics:

- Computer systems and software
- Administration, Patient management and Help support
- Calibration of template positioning and images to template registration
- Equipment set identifications and specifications (associates all equipment/instrumentation as configured for set up for implants)
- Image acquisition, import, display (2D and 3D) from various modalities (ultrasound, MR, CT Fluoroscopy)
- Contouring and anatomical identification
- Identification and loading of radiation source and placement with image guidance (low dose radiation (LDR) and HDR)
- Dose calculation (LDR and HDR)
- Printing reports

Verification and validation testing was performed using RadVision Dose Planning and Treatment System. RadVision passed all the verification and validation tests successfully.

Based on verification and validation test results and analysis of similarities and differences between the technological characteristics of the devices, RadVision is substantially equivalent to the stated predicate devices without raising new safety and/or efficacy issues.

(7) **Technological Characteristics:**

The intended use statement of RadVision is respectfully similar to the intended use statement of the predicate devices. RadVision is a Brachytherapy treatment planning software compatible with both LDR and HDR delivery systems, whereas Interplant and VariSeed 7.1 are for LDR and Varian BrachyVision 6.0 for HDR. There are no substantial differences between RadVision and Interplant and Variseed 7.1 for permanent seed implant functions and between RadVision and Varian BrachyVision for HDR functions.

The level of concern for RadVision software is major. FDA considers software contained in radiation therapy devices to be Major level of concern. RadVision is not intended for diagnostic purposes, nor will it control the delivery of the treatment plan to the patient.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Acoustic MedSystems, Inc.
% Ms. Jennifer Williams
Official Regulatory Correspondent
208 Burwash Avenue
SAVOY IL 61874

July, 16, 2013

Re: K131428
Trade/Device Name: RadVision
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXX, MUJ
Dated: April 29, 2013
Received: May 22, 2013

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

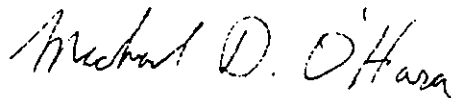
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Michael D. O'Hara". The signature is written in a cursive, flowing style.

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131428

Device Name: RadVision

Indications for Use:

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Burdette Medical Systems, Inc Interplant K982696	Varian Medical Systems BrachyVision 6.0 K992762	Varian Medical Systems VariSeed 7.1 K030534
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Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131428